REMARKS

The Notice of Appeal filed August 28, 2005, in the above-identified application is noted. Notwithstanding 37 C.F.R. § 41.33(a), entry of the present amendments is clearly proper in view of the concurrently filed RCE Transmittal, for which the present amendments constitute the necessary Submission under 37 C.F.R. § 1.114.

Applicants have amended their claims in order to further clarify the definition of various aspects of the present invention. Specifically, Applicants have amended claim 1 to recite that a "peptide" (II) having a free amino group and being a pharmaceutical compound is reacted with the sugar (III) having the reducing power and selected from the group A, with the group A consisting of lactose, sialyllactose and compounds prepared by chemically binding a polymer selected from the group consisting of polyoxyethylene, polyglutamic acid and polyvinylpyrrolidone to a hydroxyl group other than the hydroxl group formed from the reducing aldehyde group of sugar selected from the group consisting of lactose and sialyllactose. In addition, claims 2, 3, 5, 9, 13, 17, 23 and 61-80 are presently being cancelled without prejudice or disclaimer, whereby claims 2, 3, 5-20 and 22-80 have now been cancelled without prejudice or disclaimer. Moreover, claim 4 has been amended to be consistent with claim 1, in reciting the peptide (II); and claim 21 has also been amended to recite the "peptide" (II).

In addition, Applicants are adding new claims 81-98 to the application. Various of these claims recite that the compound (I) is an unmodified compound (I) modified with a pharmaceutical carrier and which is obtained by specified processing; that the compound (I) is an unmodified compound (I) modified with a

pharmaceutical carrier and which is obtained by another series of processing steps; that the compound (I) is encapsulated in a pharmaceutical carrier and is obtained by specified processing steps; and that the compound (I) is encapsulated in a pharmaceutical carrier and is obtained by other processing steps. Note, for example, claims 81-84, 86-89, and 91-94. Moreover, claims 85, 90 and 95, dependent respectively on any one of claims 81-84, 86-89 and 91-94, recite that the pharmaceutical carrier is selected from the group consisting of liposome, lipid emulsion, microemulsion, polymer micelle, microcapsule, microspher and magnetic particles. Note, for example, pages 3-6 of Applicants' specification. Also, claims 96-98, dependent respectively on claims 1, 4 and 21, recite that group A consists of lactose and sialyllactose.

The objection to the claims - minor formalities, set forth on pages 2 and 3 of the Office Action mailed February 28, 2005, is noted. Each of the claims containing minor informalities and objected to by the Examiner has been cancelled without prejudice or disclaimer; in addition, the present claim amendments, and newly added claims, have been prepared in light of these objections. In view of present amendments to the claims, it is respectfully submitted that the objection is moot.

The rejection of claims under the second paragraph of 35 U.S.C. §112, as being indefinite, set forth in Item 13 on pages 5 and 6 of the Office Action mailed February 28, 2005, is noted. Initially, note that Applicants have amended claim 1 in order to further clarify the defined pharmaceutical preparation. In particular, claim 1 has been amended to recite that the compound (I) is obtained by reacting the peptide (II) with the sugar (III), the sugar (III) being defined as selected from group A,

group A being defined. In view of amendments to claim 1, it is respectfully submitted that claim 1 is sufficiently clear so as to satisfy requirements of the second paragraph of 35 U.S.C. §112.

In addition, and consistent with suggestions by the Examiner in the first sub-paragraph of Item 13, on page 5 of the Office Action mailed February 28, 2005, Applicants have cancelled various of the previously considered claims, and have split claim 5 in four different ways, similarly claiming the subject matter of claims 17 and 23.

In view of canceling of various of the previously considered claims, it is respectfully submitted that the various bases for rejection of claims under the second paragraph of 35 U.S.C. §112, set forth in the last four sub-paragraphs on page 5, and the first two sub-paragraphs on page 6, of the Office Action mailed February 28, 2005, are moot.

Applicants respectfully traverse the rejection of their claims under the first paragraph of 35 U.S.C. §112, as set forth in Items 8 and 11 on pages 3 and 4 of the Office Action mailed February 28, 2005, especially insofar as this rejection is applicable to the claims as presently amended.

Note that the present claims recite a pharmaceutical preparation comprising a specified compound (I) obtained by reacting a peptide (II) having a free amino group and being a pharmaceutical compound, with a sugar (III) having reducing power and selected from a specifically defined group A. It is respectfully submitted that this pharmaceutical preparation as defined in present claim 1, and as more specifically defined, for example, in claims 4 and 21, and claims 96-98, is commensurate in

scope with the enabling disclosure, and thus satisfies the enablement requirement of the first paragraph of 35 U.S.C. §112. See especially claims 4, 21 and 96-98.

It is emphasized that all of the claims recite that the compound (I) is obtained by reacting a peptide (II) having a free amino group and being a pharmaceutical compound, with a sugar (III) having reducing power and selected from a group A, and the group A from which the sugar (III) is selected has also been defined. Thus, Applicants have clearly further defined the compounds having a free amino group, as well as the sugars having reducing power, consistent with the description in Applicants' original disclosure. In this regard, note comments by the Examiner in Item 5 on page 2 of the Office Action mailed April 1, 2004, in the above-identified application.

In Item 11 on page 4 of the Office Action mailed February 28, 2005, the Examiner sets forth a new basis of rejection, that from the record of the presently filed written disclosure, the specification does not reasonably provide evidence of the claimed invention "because the written disclosure exemplifying composition...shows a compound formed as a result of reaction between lactose or sialyllactose and insulin". However, attention is respectfully directed to Applicants' disclosure as a whole, including the description in the paragraph bridging pages 3 and 4 of Applicants' specification that there "is no specific restriction as to the compounds having a free amino group to be used in the present invention"; the description in Applicants' specification in the second full paragraph on page 5, that "any sugars having the reducing power can be used", suitable sugars including lactose and sialyllactose; and the description of various pharmaceutical carriers as set forth in

the paragraph bridging pages 5 and 6 of Applicants' specification. It is to be noted that the Examiner has not set forth any reasoning or evidence casting doubt on averments made by Applicants in their specification, as to materials which can be utilized according to their invention. Accordingly, it is respectfully submitted that Applicants have provided an enabling disclosure, particularly with respect to the scope of the present claims. See In re Bowen, 181 USPQ 48 (CCPA 1974); and In re Dinh-Nguyen, 181 USPQ 46 (CCPA 1974).

The contention by the Examiner in the last full paragraph on page 4 of the Office Action mailed February 28, 2005, that undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary to delineate a pharmaceutical compound made by reacting aldehyde group of lactose or sialyllactose with the amino group of a compound comprising doxorubicin together with insulin or enkephalin, together with limited amount of guidance and limited number of working examples in the specification, nature of the invention, state of the prior art, relative skilled of all those in the art, predictability or unpredictability in the art, and breadth of the claims, is noted. The present claims recite a peptide, and do not recite doxorubicin. Moreover, it is respectfully submitted that one of ordinary skill in the art could easily select various components within the components set forth in the present claims, to provide a pharmaceutical preparation as in the present claims, utilizing guidance in Applicants' specification. While some experimentation may be necessary, it is emphasized that not all experimentation is forbidden, only undue experimentation. It is respectfully submitted that undue experimentation would not be required under the present circumstances in light of

the limited number of materials set forth in the present claims and the reaction scheme according to the present invention. See In re Angstadt, 190 USPQ 214 (CCPA 1976).

The further contention by the Examiner in the last full paragraph on page 4 of the Office Action mailed February 28, 2005, that undue experimentation would be required because from the record of the present disclosure there is no showing of a compound comprising doxorubicin together with a free amino group comprising moiety, wherein the free amino group comprising moiety is a peptide and the peptide is one of insulin or enkephalin, is noted. However, note that the present claims now recite a peptide (II); accordingly, contentions by the Examiner in connection with "doxorubicin" are inapposite in connection with the present claims reciting the peptide.

To emphasize, it is noted that presently amended claim 1 does not recite either "all compounds having a free amino group" or "a compound comprising doxorubicin together with insulin, or doxorubicin together with enkephalin". Accordingly, contentions by the Examiner in connection with doxorubicin are inapposite in connection with the presently claimed subject matter.

Furthermore, attention is respectfully directed to claims 96-98, reciting that group A is selected from lactose and sialyllactose. Surely, these claims are supported by an enabling disclosure, noting, for example, page 5 of Applicants' specification, and the Examples starting on page 7 thereof.

In view of the concurrently filed RCE Transmittal and notwithstanding part of submission of the Notice of Appeal filed August 29, 2005, entry of the present amendments, and reconsideration and allowance of all claims remaining in the application, are respectfully requested.

To the extent necessary, Applicants petition for an extension of time under 37 CFR 1.136. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to the Antonelli, Terry, Stout & Kraus, LLP Deposit Account No. 01-2135 (Docket No. 506.40278X00), and please credit any excess fees to such Deposit Account.

Respectfully submitted,

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